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Exhibit #5 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number is: K102741

1. Date Prepared: April 05, 2011

2. Sponsor Information

ShanDong WeiGao Group Medical Polymer Co., Ltd
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Weihai City, Shangdong, China

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3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Consulting Co., Ltd
P.O. BOX 237-023
Shanghai, 200237, China

4. Device Name and Classification:

Device Trade Name: Enteral Feeding Bag and Set;
Classification Name: Tubes, gastrointestinal (and accessories);
Classification: Class II;
Product Code: KNT;
Regulation Number: 21 CFR 876.5980;
Review Panel: Gastroenterology/Urology

Premarket Notification Submission -510(k) Summary

5. Predicate Device Identification:

510(k) Number: K061432;

Predicate Device Name: Hospira Enteral Feeding Sets;

6. Intended Use:

Enteral Feeding Bag and Set is intended to delivery, via a feeding pump, liquid nutrition formulas to an enteral access device (e.g. a feeding tube).

7. Device Description:

The proposed device, Enteral Feeding Bag and Set, has two models: one is enteral feeding set integrated with bag, the other is an individual enteral feeding set with a puncture needle which can be used along with other pre-filled formula container.

Other components include:

- Roller Clamp, which is used to adjust the feeding rate;
- Tubings, which are used to connected components;
- Drip Chamber, which is intended for the user to observe the feeding condition;
- Echelon Fitting, which is a non-luer fitting, to connect Enteral Access Device. This fitting is provided to avoid mis-connection with I.V. devices.

8. Test Conclusion resignation

Laboratory testing was conducted to validate and verify that disposable infusion set met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:

The proposed device, Enteral Feeding Bag and Set, is substantially equivalent to the predicate device, Hospira Enteral Feeding Sets.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Shandong Weigao Group Medical Polymer Co., Ltd.
% Ms. Diana Hong, General Manager
Shanghai Midlink Consulting Co., Ltd.
P.O. Box 237-023
SHANGHAI 200030
CHINA

NOV - 8 2011

Re: K102741

Trade/Device Name: Enteral Feeding Bag and Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: October 15, 2011
Received: October 19, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

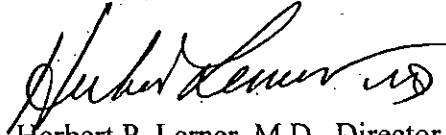
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #6 Indication for Use Form

510(k) Number: K102741

Device Name: Enteral Feeding Bag and Set

Indications for Use:

Enteral Feeding Bag and Set is intended to deliver, via a feeding pump, liquid nutrition formulas to an enteral access device (e.g. a feeding tube).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

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